MAR 2 1 2008

Exhibit B 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) r	number is:
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1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888 Fax: +86 755 2658 2680

Contact Person:

Li Dongling Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: January 31, 2008

2. Device Name: M5 Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

M5 Diagnostic Ultrasound System is substantially equivalent to the following devices: Mindray DC-6 (K#072164), GE Logiq 9 (K#061129) and GE Logiq E diagnostic ultrasound system (K#072797), Mindray DP-6600 (K#060949).

4. Device Description:

The M5 is a portable general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power-Mode, Dirpower-Mode or the combined mode (i.e. B/M-Mode). This system is a Track 3 device that employs an array of probes that include linear array and convex linear array with a frequency range of approximately 2.5 MHz to 14 MHz.

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of fetal, abdominal, pediatric, neonatal cephalic, cardiac, small parts, transvaginal, transrectal, peripheral-vascular, muscular-skeletal(conventional and superficial).

6. Safety Considerations:

The M5 Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 1997. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the M5 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.

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'APR - 8 2008

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. c/o Robert Mosenkis Citech 5200 Butler Pike Plymouth Meeting, PA 19462-1298

Re: k080640

Trade/Device Name: M5 Diagnostic Ultrasound System

Regulation Number: 21 CFR 1550

Regulation Name: Ultrasonic pulsed Doppler imaging system

Regulatory Class: Class II Product Code: IYN IYO ITX

Dated: March 4, 2008 Received: March 6, 2008

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of March 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M5 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5s

6C2s

6CV1s

7L4s

7L6s

10L4s 6LE7s 6LB7s

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D., at (240) 276-3666.

Sincerely yours,

Mancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation Center for Devices and Radiological Health

Enclosures

Mindray Co. Ltd.- M5 Diagnostic Ultrasound System

ystem	×			Trans	ducer _					
/lodel:		M	5							
Number(s) Numb										
						 				
<u> </u>										
Clinical Application	A	В	М		CWD			Velocity		Other (specify)
Ophthalmic										
Fetal		N	N	N		N			<u> </u>	
Abdominal		N	N	N		N	N		N	Note 1, 2, 3
Intraoperative (specify)*										
Intraoperative Neurological					<u> </u>					
Pediatric		N	N	N		N	N			Note 1, 2, 3
Small organ(specify)**		N	N	N		N	N		N	Note 2, 3
Neonatal Cephalic		N	N	N		N	N		N	Note 2, 3
Adult Cephalic		N	N	N		N	N		N	Note 2, 3
Cardiac		N	N	N		N	N		N	Note 2, 3
Transesophageal							<u></u>	<u></u>		
Transrectal		N	N	N		N	N		N	Note 2
Transvaginal		N	N	N		N	N		N	Note 2, 3
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N	Note 2, 3
Laparoscopic			Ĭ							
Musculo-skeletal Conventional		N	N	N		N	N		N	Note 2, 3
Musculo-skeletal Superficial		N	N	N		N	N		N	Note 2, 3
Other (specify)***		N	N	N		*N	N		N	Note 2, 3
N=new indication; P-previously	clear	ed by	FDA;	E=ad	ded und	er Appendí	хE			
Additional comments:Combined	mod	es: B+	M, P	V+B,	Color+	B, Power +	B, PW +Col	or+ B, Pov	ver + PW +B	
*Intraoperative inclu	des ai	odomi	nal, ti	oracio	, and va	scular etc.	· · · · · · · · · · · · · · · · · · ·			
**Small organ-breas	t, thy	oid, te	stes,	etc.	•	·····				
***Other use include	s Urd	logy/l	Prosta	te.				3		
Note 1: Tissue Harm	onic I	magin	g. Th	e feat	ire does	not use cor	itrast agents.	· ·		

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Note 3: iScape

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

K080640 nn48

Mindray Co. Ltd. - M5 Diagnostic Ultrasound System

System		-		Trans	ducer	×				
Model:		3C	5s							
510(k) Number(s)							•			
					, 					
		_				Мо	de of Opera	ition		
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 1, 2, 3
Abdominal		N	N	N		N	N		N	Note 1, 2, 3
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 1, 2, 3
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal							•			
Transrectal .				T						
Transvaginal					<u> </u>					
Transurethral				1						
Intravascular										
Peripheral Vascular				T						
Laparoscopic				Ī						
Musculo-skeletal Conventional	1			Ţ						
Musculo-skeletal Superficial										
Other (Urology)						-				
N=new indication; P=previously	y clear	ed by	FDA	E=ad	lded und	er Appendi	хE			<u> </u>
Additional comments:Combined	d mod	es: B+	M, P	W+B,	Color +	B, Power	B, PW +Co	lor+ B, Pov	ver + PW +B.	
*Intraoperative inclu	ıdes al	odomi	nal, ti	oraci	c, and va	scular etc.				
Small organ-breas	st, thyr	roid, to	estes,	etc.		*************************************	***			
Note 1: Tissue Harm	ionic I	magir	ıg. Th	e fean	ure does	not use cor	itrast agents.	*		
Note 2: Smart3D							 		···	
Note 3: iScape										
(PLEASE DO N	W TO	/RITE	BEL	r wo	HIS LI	NE-CONTE	NUE ON AN	OTHER P.	AGE IF NEE	DED)
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Prescription USE (Per 21 C					-	(Î	My	gn-Off)	Who Abdo	minal and
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Mindray Co. Ltd. - M5 Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System _				1 rans	aucer .	<u> </u>							
Model:		6C	2s										
10(k) Number(s)													
			·										
·						Mo	de of Opera	peration					
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal													
Abdominal		N	N	N		N٠	N		N	Note 2, 3			
Intraoperative (specify)*													
Intraoperative Neurological									ļ				
Pediatric		N	N	N		N	N	ļ	N	Note 2, 3			
Small organ(specify)**									ļ				
Neonatal Cephalic		N	N	N		N ·	N		N	Note 2, 3			
Adult Cephalic		N	N	N	<u>L</u> _	N	N		N	Note 2, 3			
Cardiac		N	N	N		N	N	<u> </u>	N	Note 2, 3			
Transesophageal		<u> </u>			<u> · </u>	<u> </u>	·	ļ					
Transrectal	<u> </u>								ļ				
Transvaginal	<u> </u>				<u> </u>	_			<u> </u>				
Transurethral							<u> </u>	ļ					
Intravascular	<u> </u>	<u> </u>							<u> </u>				
Peripheral Vascular	<u> </u>								<u> </u>				
Laparoscopic	<u>L</u>		<u> </u>		 								
Musculo-skeletal Conventional	<u> </u>		<u> </u>					<u> </u>	 				
Musculo-skeletal Superficial	1		<u> </u>					<u> </u>		ļ			
Other (specify)						- 1/3 - / 1	<u> </u>		<u> </u>	<u>L</u>			
N=new indication; P=previousl													
Additional comments:Combine	d mod	les: B	⊦М, Р	W+B,	Color +	B, Power	+ B, PW +Co	lor+ B, Po	wer + PW +B				
*Intraoperative inclu	ides a	bdom	inal, t	horaci	c, and v	ascular etc.							
**Small organ-breas	st, thy	roid, t	estes,	etc.									
Note 1: Tissue Haru	nonic	Imagi	ng. Ti	ne feat	ture does	not use co	ntrast agents.	8					
Note 2: Smart3D		•								-			
Note 3: iScape	•			·									
(PLEASE DO N	7 TO	VRIT	BĘI	OW.	THIS LI	NE-CONTI	NUE ON AN	OTHER F	AGE IF NEE	DED)			
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number ...

Diagnostic Ultrasound Indications for Use Form

System				Trans	ducer	×				
Model:		6CV	/ls							
510(k) Number(s)				-						
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Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 2, 3
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric									,	
Small organ(specify)**									·	
Neonatal Cephalic										
Adult Cephalic				1						
Cardiac				1						
Transesophageal				1		Ī				
Transrectal		N	N	N		N	N		N	Note 2, 3
Transvaginal		N	N	N		N	N		N	Note 2, 3
Transurethral										
Intravascular										
Peripheral Vascular						1				
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial								}		
Other (specify)***		N	N	N		Ŋ	N		N	Note 2, 3
N=new indication; P=previously	clear	ed by	FDA	E=ac	lded und	er Appendi	хE	<u> </u>		
Additional comments:Combined	l mode	es: B+	M, P	W+B,	Color+	B, Power +	B, PW +Co	lor+ B, Pov	ver + PW +B	
*Intraoperative inclu	des at	domi	nal, tl	oraci	c, and va	scular etc.	•	·		
**Small organ-breas	t, thyr	oid, te	stes,	etc.					··· <u> </u>	
***Other use include				•				**		
Note 1: Tissue Harm	onic I	magin	g. Th	c feat	ure does	not use cor	itrast agents.	<u> </u>	· · · · · · · · · · · · · · · · · · ·	
Note 2: Smart3D								 		
Note 3: iScape										
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Mindray Co. Ltd. - M5 Diagnostic Ultrasound System

System				Trans	ducer	×				
Model:	7L4	s, 7L6	s, 101	L4s						
510(k) Number(s)		<u></u>	 							
							·			
	Mode of Operation									
Clinical Application	Α	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal								<u> </u>	<u> </u>	
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**		N	N	N	N		N		N	Note 2, 3
Neonatal Cephalic		N	N	N	N		N	·	N	Note 2, 3
Adult Cephalic										
Cardiac					1					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral						"				
Intravascular										
Peripheral Vascular		N	N	N	N		N		N	Note 2, 3
Laparoscopic	1			1.						<u> </u>
Musculo-skeletal Conventional		N	N	N	N		N		N	Note 2, 3
Musculo-skeletal Superficial		N	N	N	N		N		N	Note 2, 3
Other (specify)	T		T-							
N=new indication; P=previously	y clear	ed by	FDA	; E=ac	ided und	ler Append	ix E			
Additional comments:Combine								lor+ B, Po	wer + PW +B	•
*Intraoperative inclu										
**Small organ-breas	st, thyr	oid, t	estes,	etc.						
Note 1: Tissue Harn					ure does	not use co	ntrast agents.	** \$ *		
Note 2: Smart3D				•						
Note 3: iScape	 -						• • • • • •			
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Min ndray Co. Ltd. - M5 Diagnostic Ultrasound System

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Model:		6LE	7s		•							
510(k) Number(s)												
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	Mode of Operation											
Clinical Application	A	В	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging		Other (specify)		
Ophthalmic												
Fetal		N	N	N		N	N		N	Note 3		
Abdominal												
Intraoperative (specify)*												
Intraoperative Neurological												
Pediatric				l								
Small organ(specify)**	·				Ţ -							
Neonatal Cephalic									·			
Adult Cephalic												
Cardiac	\Box				1		1.:					
Transesophageal		ļ —										
Transrectal		N	N	N		N	N		N	Note 3		
Transvaginal	1											
Transurethral	1					1			1			
Intravascular	 											
Peripheral Vascular	1	T										
Laparoscopic		 		1	<u> </u>							
Musculo-skeletal Conventional	1			1			*					
Musculo-skeletal Superficial	1			T	1			1				
Other (specify)***		N	N	N		N	N		N	Note 3		
N=new indication; P=previousl	y clea	red by	FDA	E=ac	ided und	ler Append	ix E					
Additional comments:Combine								ior+ B, Po	wer + PW +B	•		
*Intraoperative încli												
**Small organ-breas												
***Other use includ						· · · · · · · · · · · · · · · · · · ·		*				
Note 1: Tissue Harn	nonic	Imagii	ıg. Th	e feat	ure does	not use co	ntrast agents.		•			
Note 2: Smart3D		 _					<u> </u>	····				
Note 3: iScape		<u> </u>					<u>- '</u> -					
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Prescription USE (Per 21 (CFR :	801.1	09)			Division	n Sign-Off of Repro		Abdominal	and		
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			Trans	ducer	×							
	6LB	7s		,								
		Mode of Operation M PW CWD Color Doppler Doppler Velocity Imaging Combined (specify) N N N N N N N N N N N N N N N N N N N										
A	В	М		CWD	1		Velocity		Other (specify)			
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y cleare	d by	FDA	E=ac	ided und	ler Append	ix E						
d modes	s: B+	M, P	W+B,	Color +	B, Power	+ B, PW +Co	lor+ B, Po	wer + PW +B	i.			
ides abd	lomi	nal, tl	ioraci	c, and v	escular etc.							
st, thyro	id, t	estes,	etc.									
es Urole	ogy/	Prosta	itc.				ď.					
onic In	nagir	ıg. Tl	ic feat	ure does	not use co	ntrast agents.						
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Concur	ren	ce o	f CD	RH, O	ffice of D	evice Evalu	ation(O	DE)				
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CFR 80)1.1	09)	•		(Divis	In Sign-0	(h)	Wh	γ <u> </u>			
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					Radio	logical De	vices		/ ^			
					510/	() Number	K	080	640			
	A A Cleared I modes about, thiyrous Indiana In	A B N N r cleared by des abdomist, thyroid, to see Urology/sonic Imagin	A B M N N cleared by FDA disabdominal, the third it, third, testes, as Urology/Prostationic Imaging. The	A B M PW D N N N N cleared by FDA; E=ac it, thyroid, testes, etc. es Urology/Prostate. conic Imaging. The feat	A B M PW CWD N N N N cleared by FDA; E=added unce the desabdominal, thoracic, and variety through the state of the concurrence of CDRH, Of t	Moderate Services and vascular etc. it, thiyroid, testes, etc. es Urology/Prostate. sonic Imaging. The feature does not use control of the Concurrence of CDRH, Office of December 1999.	Mode of Opera Mode of Opera Mode of Opera A B M PW CWD Color Doppler Doppler N N N N N N N N N N N N N N N N N N N	Mode of Operation A B M PW CWD Color Doppler Doppler Velocity Imaging N N N N N N N N N N N N N N N N N N N	Mode of Operation A B M PW CWD Color Doppler Velocity Imaging (specify) N N N N N N N N N N N N N N N N N N N			